

### REMARKS

The April 17, 2008, Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the April 17, 2008, Official Action. Therefore, the initial due date for response is July 17, 2008. This response is being filed within the initial 3 month response period.

As a preliminary matter, Applicant notes that the Examiner has withdrawn the previous rejection of the claims under 35 U.S.C §112, second paragraph for alleged indefiniteness. Also, the rejections of the claims under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description and enablement requirements have been withdrawn in view of the previous amendments. Additionally, the Examiner has withdrawn the rejection of claims 91-94 and 98-100 under 35 U.S.C. §102(e) since the amended claims are no longer anticipated by the prior art. Lastly, the rejection of the claims on the ground of nonstatutory obviousness-type double patenting has also been withdrawn in light of the terminal disclaimer filed by Applicant on December 3, 2007.

Turning to the substantive aspects of the April 17, 2008, Official Action, the Examiner has maintained the rejection of claims 91, 92, 96, 98, 104, and 110-112 under 35 U.S.C. §102(a) as allegedly anticipated by Hu et al. as evidenced by Jiang et al.

At page 4 of the Official Action, claims 91 and 110

remain rejected under 35 U.S.C. §102(b) as allegedly anticipated by Schultz et al., as evidenced by Oikawa et al.

The Examiner has raised a new ground of rejection for claims 93, 94, 99, 100, 105, and 106 under 35 U.S.C. §103(a). It is the Examiner's position that the aforementioned claims are allegedly unpatentable over Schultz et al., as applied to claim 91, and further in view of U.S. Patent 6,783,760.

Finally, at page 6 of the Official Action, the Examiner indicates that claims 120 and 121 are objected to as being dependent on a rejected base claim but would be allowable if rewritten to include the features of the base claim.

The foregoing objections and rejections constitute all of the grounds set forth in the April 17, 2008, Official Action for refusing the present application. In light of the amendments to the claims and the following remarks, each of the above-noted rejections is respectfully traversed. Applicant submits that the claims, as presently amended, are in condition for allowance.

**CLAIMS 91, 92, 96, 98, 104 AND 110-112, AS AMENDED,  
ARE NOT ANTICIPATED BY HU ET AL. AS EVIDENCED BY JIANG ET  
AL.**

The Examiner has maintained the rejection of claims 91, 92, 96, 98, 104, and 110-112 under 35 U.S.C. §102(a) as allegedly anticipated by Hu et al. (Clin. Can. Res. (2000) 6:880-886), as evidenced by Jiang et al. (PNAS (2002) 97:1749-1753).

Applicant respectfully submits that Hu et al. fails to disclose a method identical to that which is presently

recited in amended claim 91. Indeed, the Examiner indicated that claims 120 and 121 contain allowable subject matter, but were objected to for being dependent on a rejected base claim. In response, Applicant has canceled claim 121 and added the features of this claim (i.e., "assessing inhibition of angiogenesis following administration of said PI-3 kinase inhibitor") to claim 91. It is submitted that this amendment places claim 91 and claims dependent therefrom in condition for allowance.

The Examiner has rejected claim 104 asserting that the subject matter of this claim is anticipated by Hu et al., as evidenced by Jiang et al. Applicants respectfully submit that this rejection is untenable and should be withdrawn. At the outset, claim 104 has been cancelled and a new independent claim added, claim 122 which incorporates the features of claim 104 and original claim 91. Clearly, the subject matter of new claim 122 cannot be considered to raise a new issue for search or consideration as the claim literally recites the features of claims 91, and 104, i.e., previously searched subject matter.

New claim 122 recites the feature that the cancer is "radioresistant," and states that administration of the PI-3 kinase inhibitor enhances the "radiosensitivity of cells in said cancer." Neither Hu et al. nor Jiang et al. expressly disclose radioresistant cancer, nor is there any basis to conclude that radioresistance would be an inherent feature. As such, at least for this reason, there can be no anticipation. In addition, both of the references relied on by the Examiner, Hu et al. and Jiang et al., are silent regarding the ability of a PI3 kinase inhibitor to enhance the radiosensitivity of a radioresistant cancer. Therefore, it cannot reasonably be maintained that these

references serve as anticipatory prior art since they do not disclose all the features recited in the claim.

In view of the foregoing remarks and claim amendments, Applicant respectfully submits that the rejection of claims 91, 92, 96, 98, 104 and 110-112 under 35 U.S.C. §102(a) is untenable and request its withdrawal.

**CLAIMS 91 AND 110, AS AMENDED, ARE NOT ANTICIPATED BY  
SCHULTZ ET AL. AS EVIDENCED BY OIKAWA ET AL.**

Claims 91 and 110 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schultz et al. (Anticancer Res. (1995) 15(4):1135-1139) as evidenced by Oikawa et al. (Eur. J. Pharm. (1996) 318:93-96).

As discussed above with regard to Hu et al., and Jiang et al., claim 91 as amended includes the feature of claim 121 which the Examiner has indicated is allowable over the prior art. For at least this reason, Applicant submits that the Examiner's rejection based on Schultz et al., as evidenced by Oikawa et al., is improper and should be withdrawn.

**CLAIMS 93, 94, 99, 100, 105, AND 106, AS AMENDED, ARE NOT  
UNPATENTABLE OVER SCHULTZ ET AL., AS APPLIED TO CLAIM 91,  
IN FURTHER VIEW OF THE '760 PATENT**

The Examiner has raised a new ground of rejection of claims 93, 94, 99, 100, 105, and 106 under 35 U.S.C. §103(a) as allegedly being unpatentable over Schultz et al., as applied to previously presented claim 91, in further view of the '760 patent.

It is the Examiner's position that "because Schultz et al., teach that Wortmannin has been used to treat tumor [sic] and US 6783760 B1 teach etoposides has [sic] also

been used to treat tumor [sic]." "Combining two known anti-cancer treatments treating [sic] cancer is obvious." Applicants respectfully disagree with the Examiner's position for the reasons set forth below.

By way of background, the Examiner bears the burden of establishing a prima facie case of obviousness. In re Rijckaert, 28 U.S.P.Q.2d 1934, 1935 (Fed. Cir. 1993). To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some reason, either present in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. M.P.E.P. §2143.01; In re Dow Chem. Co., 5 U.S.P.Q.2d 1929 (Fed. Cir. 1988). Second, a reasonable expectation of success must exist. M.P.E.P. §2143.02. Third, the prior art reference or references, taken alone or combined, must teach or suggest each and every element recited in the claims. M.P.E.P. §2143.03. Moreover, each of these requirements must "be found in the prior art, and not based on applicant's disclosure." M.P.E.P. §2143; In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

Applicant submits that in light of the amendment made to independent claim 91, which is discussed above, the prior art references cited by the Examiner do not teach or suggest every element recited in the claims. More specifically, the art cited by the Examiner is silent with respect to the method step of "assessing inhibition of angiogenesis following administration of said PI-3 kinase inhibitor." Additionally, the Examiner has provided no evidence which suggests or motivates the skilled artisan to combine the references to result in the presently claimed

invention, thus no prima facie case of obviousness has been established. Consequently, for at least these reasons, the Examiner's rejection of the claims under Section 103(a) is not valid and should be withdrawn.

#### CONCLUSION

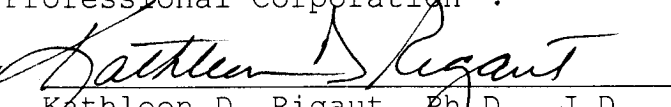
It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the rejections set forth in the April 17 2008 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,  
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By

  
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